OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

POST-IRB APPROVAL
FDA DRUG (IND) SPONSOR AND INVESTIGATOR RESPONSIBILITY (21 CFR312)

Purpose: Investigators who initiate and submit an IND application to the FDA assume the responsibilities of both the investigator and the sponsor. Under FDA regulations, an academic sponsor or sponsor-investigator has the same obligations as a multi-national pharmaceutical manufacturer that sponsors or holds an IND.

This form is for Sponsor-Investigators to conduct a self-assessment of their IRB approved studies to ensure that they are meeting their institutional and regulatory requirements. Onsite documents (listed in the right column) correspond to the regulations written in 21 CFR 312 (drugs, biologics) and the institutional policy and can provide evidence that the Sponsor-Investigator has fulfilled his/her responsibilities. Depending on the specific study, additional documents may be needed.

The Office of Research Compliance Review (ORCR) recommends using this checklist during study initiation and as an ongoing internal review tool. For more information or questions, please contact: orcr-deptemail@umich.edu.

Additional information on sponsor-investigator responsibilities can be found on the following websites: OM Part 8: Studies Regulated by FDA & Use of Investigational Articles; MIAP IND/IDE Consultation & Development; MICHR Study Monitoring; IRBMED Guidance on Federal Regulations

STUDY INFORMATION	
HUM #	
Study Title	
PI Name	
Date Self-Assessment Completed	
Person Completing Self-Assessment	

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
TRAINING Completed the required U-M educational session for Sponsor-Investigators	MIAP training sign-in sheet completed	Yes ◯ Date:	No ◯
CLINICALTRIALS.GOV Completed registration of the protocol on Clinicaltrials.gov Registration date within 21 days of the first subject being enrolled. The consent form contains the mandatory language.	Form 3674 (Certificate of Compliance) submitted to FDA Registration within 21 days of first subject enrollment IRB approved consent form	Yes ◯ Yes ◯ Yes ◯	No ◯ No ◯ No ◯
MAINTAIN AN EFFECTIVE IND (consult with MICHR/MIAP and consider using their services for document preparation assistance, application review, and maintenance of an active IND) Protocol amendments are required for (21 CFR 312.30) New protocol Changes to existing protocol New investigator	Original IND application (including 1571) FDA letter of no objection, if provided Amendments (with 1571) Other correspondence with FDA (e.g. response to a clinical hold, general correspondence)	Yes ◯ Yes ◯ Yes ◯ Yes ◯	No ◯ No ◯ No ◯ No ◯
Information amendments (21 CFR 312.31) Essential information not within the scope of a protocol amendment (e.g. new technical information, discontinuation of clinical investigation).	Amendments (with 1571)	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
IND safety reports (21 CFR 312.32) Serious, related, unexpected or significant preclinical findings (written reports, e.g. MedWatch 3500A to FDA, and all participating investigators if applicable within 15 calendar days)	IND safety reports (with 1571) Evidence of correspondence to other investigators	Yes ◯	No ◯
Fatal or life-threatening reports (telephone or FAX within 7 calendar days)	IND safety reports (with 1571) Evidence of correspondence to other investigators	Yes ◯	No ◯
Follow-up information to a safety report (submitted as soon as available)	IND safety reports (with 1571) Evidence of correspondence to other investigators	Yes ◯	No ◯
Annual reports (21 CFR 312.33) Within 60 days of the anniversary date that the IND went into effect	Annual report (with 1571)	Yes ◯	No ◯
INFORMING INVESTIGATORS (21 CFR 312.55) Provide all clinical investigators with Investigator's Brochure (IB)	Current Investigator's Brochure or approved label	Yes ◯	No ◯
	For multi-site studies: Documentation that all sites have received the Investigator Brochure	Yes ◯	No ◯
Inform investigators of new observations discovered by or reported to the sponsor on the investigational product.	Documentation of communication with investigators regarding new observations and adverse events	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
SELECT QUALIFIED INVESTIGATORS AND MONITORS (21 CFR 312.53; 312.57(b)) Select PIs qualified by training and experience	Signed FDA Form 1572/Investigator Agreement	Yes ◯	No ◯
	Current Investigator CV and license	Yes ◯	No ◯
Keep accurate records of financial disclosure according to 21 CFR 54	IRB approval letter	Yes ◯	No ◯
	Financial disclosure from such as FDA form 3455 for PI and Co-Investigators listed on 1572/Investigator Agreement	Yes ◯	No ◯
Ship investigational product only to those investigators participating in the trial	*Multi-site studies (applies to training and shipping investigational product):* Investigator information is required for **each** site.	Yes ◯	No ◯
	FDA Form 1572 and PI CV is provided to FDA	Yes ◯	No ◯
Select monitors qualified by training and experience	*For Monitoring of Study:* MICHR Monitoring Services	Yes ◯	No ◯
	Other (specify):		
	CV and training experience of monitor	Yes ◯	No ◯
	Ensure monitor is trained on protocol	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

SPONSOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
ENSURE ONGOING MONITORING (21 CFR 312.56) Ensure proper monitoring Ensure PI compliance or discontinue shipments of investigational drug Review and evaluate drug safety and effectiveness Discontinue investigation within 5 working days when unreasonable and significant risks to subject are identified.	Documentation of safety monitoring plan	Yes ◯	No ◯
	Who will be reviewing safety data:		
	Sponsor (or sponsor-investigator)	Yes ◯	No ◯
	DSMB	Yes ◯	No ◯
	External medical monitor	Yes ◯	No ◯
	Other (specify):		
	Reports/meeting minutes from DSMB and/or medical monitor	Yes ◯	No ◯
	Documentation of data monitoring	Yes ◯	No ◯
	Research team has been trained on data collection sheets and/or CRFs	Yes ◯	No ◯
	Correspondence with monitor	Yes ◯	No ◯
	Documentation of monitoring	Yes ◯	No ◯
	Timely notifications to all investigators, IRB and FDA if investigation discontinued.	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

SPONSOR RESPONSIBILITIES
COMMENTS ON SPONSOR RESPONSIBILITIES:

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

INVESTIGATOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
Assure IRB review and approval and prompt reporting of any changes or problems involving risk to subjects (21 CFR 312.66)	Initial IRB approval	Yes ◯	No ◯
	Scheduled continuing review (SCR)	Yes ◯	No ◯
	Amendments describing any study changes	Yes ◯	No ◯
	Adverse event reports according to IRBMED guidance or study specific plan	Yes ◯	No ◯
	Unanticipated problems (UaPs)	Yes ◯	No ◯
	Protocol deviations reported to the IRB (ORIOs)	Yes ◯	No ◯
	Current Investigator's Brochure	Yes ◯	No ◯
	Other IRB correspondence	Yes ◯	No ◯
Maintain adequate and accurate case histories on each subject's participation in the trial (21 CFR 312.62(b))	Signed and dated consent forms for all subjects	Yes ◯	No ◯
	Supporting data (source documents)	Yes ◯	No ◯
	Case report forms (CRFs)	Yes ◯	No ◯
	Subject eligibility documentation	Yes ◯	No ◯
	Progress notes	Yes ◯	No ◯
	Concomitant medications recorded	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

INVESTIGATOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
Obtain informed consent in accordance with provisions in 21 CFR50	IRB approved consent form document that includes all required elements	Yes ◯	No ◯
Supervise the conduct of the clinical investigation (21 CFR 312.60) ensuring: Appropriate delegation of tasks Adequate training to protocol Adequate supervision	Delegation log	Yes ◯	No ◯
	Staff training log	Yes ◯	No ◯
	Minutes from research team meetings to review trial progress, AEs, protocol changes	Yes ◯	No ◯
	Notes from meetings with study monitor	Yes ◯	No ◯
	Written procedures for internal review of data	Yes ◯	No ◯
Protect the rights, safety and welfare of study subjects (21 CFR 312.60)	Adhere to protocol	Yes ◯	No ◯
	Provide reasonable medical care for AEs	Yes ◯	No ◯
	Inform subject when medical care is needed for conditions unrelated to research	Yes ◯	No ◯
	Investigator is available to subjects during conduct of study	Yes ◯	No ◯
	Appropriate delegation to co-investigators if PI is not available	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

INVESTIGATOR RESPONSIBILITIES			
Regulations	**Corresponding Onsite Documents**	**Response**	
Investigator is responsible for providing sponsor with reports (21 CFR 312.64) Progress reports Safety reports Deviations from investigational plan Final reports Financial disclosure reports	Investigator has provided sponsor with pertinent correspondence (enrollment numbers, adverse events, protocol deviations, financial information, any changes in financial information, and protocol deviations).	Yes ◯	No ◯

INVESTIGATOR RESPONSIBILITIES
COMMENTS ON INVESTIGATOR RESPONSIBILITIES:

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

DRUG ACCOUNTABILITY			
Regulations	**Corresponding Onsite Documents**	**Response**	
Sponsor is responsible for record of drug disposition (21 CFR 312.57, 312.59) Maintain adequate record of receipt and shipment of investigational drug Assure return of all unused investigational drug from individual investigators participating in the trial or authorize alternative disposition of unused product. Maintain written records of any disposition of drug	*Receipt:* Drug received from industry. Drug accountability log includes:		
	Receipt date	Yes ◯	No ◯
	Quantity	Yes ◯	No ◯
	Lot #	Yes ◯	No ◯
	Return/disposition	Yes ◯	No ◯
	Method of disposal	Yes ◯	No ◯
	Drug manufactured and/or compounded on-site	Yes ◯	No ◯
	Shipment: Single center study – no drug shipment	Yes ◯	No ◯
	If delegated to a drug depot (in multi-site study) outside U-M research pharmacy, ensure that they have:		
	Date	Yes ◯	No ◯
	Destination	Yes ◯	No ◯
	Who shipped	Yes ◯	No ◯
	Quantity	Yes ◯	No ◯
	Lot #	Yes ◯	No ◯
	Return/disposition	Yes ◯	No ◯
	Method of disposal	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

DRUG ACCOUNTABILITY			
Regulations	**Corresponding Onsite Documents**	**Response**	
Investigator is required to maintain adequate records of the disposition of the drug (21 CFR 312.62)	*Research Pharmacy will manage drug.* Drug dispensing record includes: Date Lot # Quantity ID of subject administered Disposition/record of return ID of person dispensing Return of drug: Count Reason	Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯ Yes ◯	No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯ No ◯
Investigator is responsible to ensure control of investigational drug (21 CFR 312.61) Drug will be administered only to those subjects enrolled in the clinical study and under investigator or designee's supervision.	Enrollment / randomization log Delegation of responsibility log	Yes ◯ Yes ◯	No ◯ No ◯

DRUG ACCOUNTABILITY
COMMENTS ON DRUG ACCOUNTABILITY:

RECORD RETENTION			
Regulations	**Corresponding Onsite Documents**	**Response**	
Sponsor and Investigator requirement for inspection of investigator's records and reports: Upon request, permit University, FDA officer and/or other governmental officials to access copy and verify any records or reports made by the investigator to ensure that the study is conducted in a safe and proper manner. When contacted by the FDA to schedule an inspection (or the FDA has arrived without advance notice), the PI or a member of the research team is expected to immediately contact the following offices: Office of Regulatory Affairs and IRB of Record. The following offices may also need to be notified at the earliest opportunity: Office of the General Counsel U-M Office of Research MIAP Sponsor (if other than Principal Investigator)	Records on file	Yes ◯	No ◯

OFFICE OF RESEARCH COMPLIANCE REVIEW
UNIVERSITY OF MICHIGAN

RECORD RETENTION
COMMENTS ON RECORD RETENTION: